

Speaking Plainly: Communicating the Patient's Role in Health Care Safety

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Abstract

The development and testing of a patient fact sheet entitled *Five Steps to Safer Health Care* illustrate important research considerations associated with the process of crafting messages to help patients reduce health care system errors and improve the safety of their care. The basis for the fact sheet was a larger set of messages drawn from a review of the health care literature by the Agency for Healthcare Research and Quality. Researchers at the Centers for Medicare & Medicaid Services conducted testing to determine which messages resonated with Medicare beneficiaries, explored the beneficiaries' relationships with their health care providers, and considered how that context might affect their responses to the messages. Researchers tested the resulting patient fact sheet with physicians to better understand their potential reactions and to formulate strategies for disseminating and promoting the product. Potential cultural differences were identified and discussed with Spanish-dominant consumers (i.e., persons who prefer speaking in Spanish, regardless of their ability to speak English) to enhance development of an effective Spanish-language version of the patient fact sheet. This body of research studies suggested not only which messages to emphasize, but also which secondary audiences to target, and how Spanish-dominant consumers might differ from others in their understanding and use of these health messages. Findings from these studies also indicated some opportunities for and barriers to promoting the messages.

Introduction

Five Steps to Safer Health Care is a fact sheet¹ designed to educate patients on specific behaviors they can perform to improve their own safety. The development of the fact sheet and the related promotional strategy and materials illustrates some research considerations that may aid others as they try to engage particular audiences in patient safety-conscious behaviors. This paper describes the history and research behind that development. It also will present the patient fact sheet, annotated with decisions key to its creation and modification. Finally, this paper discusses the implications for other patient-focused safety endeavors.

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Background

Since 1999, agencies of the Federal Government have been responding to the Institute of Medicine's (IOM) landmark report, *To Err Is Human*,² which documented the enormous human and financial costs of preventable medical errors that occur regularly throughout the health care system.

One week after the IOM report was released, the President directed the Quality Interagency Coordination Task Force (QuIC), a coalition of Federal agencies concerned with health care quality, to prepare a response to the report, including recommendations for actions to improve patient safety.

Anticipating that the QuIC response would generate an influx of questions regarding how patients might help to prevent medical errors, the Agency for Healthcare Research and Quality (AHRQ) launched a review of the relevant research literature. The evidence, though relatively sparse at that time, nevertheless was sufficient to support a fact sheet for patients and other consumers, entitled *20 Tips to Help Prevent Medical Errors*.³ Some of the tips amounted to general exhortations, such as the notion that “more” (treatment) is not necessarily “better.” Some of the tips recommended general categories of behavior, such as being an active member of one’s own health care team. Others specified particular actions that patients could take to avoid errors, such as maintaining a current list of all medications. Still other tips aimed to indirectly change provider behavior through the actions of patients (e.g., asking health care providers if they have washed their hands). The tips also varied in terms of their focus on medications, hospital stays, or surgeries.

AHRQ released the *20 Tips to Help Prevent Medical Errors* fact sheet in March of 2000, concurrent with the Federal response to the IOM report. The document was cited in news coverage of Federal efforts to address the IOM report’s recommendations, and a variety of public- and private-sector groups soon put the fact sheet into practice. AHRQ continues to make the *20 Tips to Help Prevent Medical Errors* available to the public through its Web site as part of a collection of online quality and safety resources known as the Quality of Care “Q-Pack” (available online at: <http://www.ahrq.gov/consumer/pathqpack.htm>).

The *20 Tips to Help Prevent Medical Errors* patient fact sheet also engendered a number of related projects, all of which are part of the “Q-Pack.” In the summer of 2000, for example, after testing messages, illustrations, and formatting options for persons with low health literacy levels, AHRQ produced an illustrated brochure entitled *Ways You Can Help Your Family Prevent Medical Errors*⁴ to better address the needs of this specific population. In December of 2002, the Agency also launched *20 Tips to Help Prevent Medical Errors in Children*,⁵ in partnership with the American Academy of Pediatrics. However, the most widely distributed product derived from *20 Tips to Help Prevent Medical Errors* is the patient fact sheet *Five Steps to Safer Health Care*.

Shortly after the release of the *20 Tips to Help Prevent Medical Errors*, the Office of Personnel Management (OPM) and other Federal agencies requested a more succinct set of tips that could be included in other documents. OPM, for

example, wanted to include a shorter tips list in its annual health plan mailings to Federal employees. With help from an existing health communications partnership sponsored by the Employee Health Benefits campaign at the Department of Labor, the QuIC developed a shorter fact sheet with input from many Federal agencies. This fact sheet eventually was named the *Five Steps to Safer Health Care*. The partnership provided additional feedback from private organizations, including the Joint Commission on the Accreditation of Healthcare Organizations, the American Hospital Association, the American Medical Association, what was then known as the Health Insurance Association of America, large health care purchasers like General Motors and General Electric, and others. These partners eventually played roles in the sponsorship and dissemination of the patient fact sheet.

Consumer testing

To better provide audiences that might use the patient fact sheet with input into its creation,⁶ researchers at the Centers for Medicare & Medicaid Services (CMS)—the agency that runs the Medicare program and that was formerly known as the Health Care Financing Administration, or HCFA—attempted to determine which of the “tips” Medicare beneficiaries were most likely to put into widespread use. (Unless otherwise specified, the term “beneficiary/ies,” refers to Medicare beneficiaries aged 65 and older, while “consumer(s)” refers to a broader range of ages and insurance types. “Consumer testing” refers to the process of testing materials or concepts with an audience.) To diversify the types of messages being considered, the researchers formulated eight additional “tips” to reflect the types of messages that other groups, such as the Leapfrog Group and the Foundation for Accountability,⁷ were considering. For example, the *20 Tips to Safer Health Care* called attention to consumer behaviors, while other groups used their messages to draw attention to the danger that medical errors posed to the public.

In the spring of 2000, the CMS researchers conducted eight focus groups with Medicare beneficiaries (n = 72, aged 65–80, selected for ethnic mix, four groups with high school education or less, and four with post-high school education) in Baltimore, MD, and Richmond, VA. The groups were used to identify persuasive error prevention messages and to identify the types of patient-provider relationships that beneficiaries most prefer.⁸ Methods included a ranking exercise and exploratory group discussions about beliefs and attitudes (those associated with medical errors as well as those related to the participants’ relationships with their health care providers). The ranking exercise was used in the final six groups, which were comprised of participants determined in advance to be moderate-to-high users of medical services.

Findings from the focus groups suggested that beneficiaries clearly preferred messages that promoted a collaborative patient-physician relationship (e.g., “Make sure your doctor knows about any allergies and adverse reactions you have to medicines”), and that they were uncomfortable with those that could be viewed

as confrontational (e.g., “If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands”).⁹ Beneficiaries also preferred messages that specified an action to be taken and a mode of implementation (e.g., “Keep a record of the medicines you take and be sure to tell your doctor about them and any allergies you might have”), as opposed to generalized exhortations (e.g., “Know that ‘more’ is not always ‘better’”). Beneficiaries also reported the assumption that the health care system takes certain error-checking steps that it may not necessarily take. For example, they indicated an unwillingness to check on medications dispensed by pharmacists (e.g., “When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?”), because they believed that prescription accuracy is routinely verified.

The public-private partnership considered the aforementioned findings and other input as it crafted the *Five Steps to Safer Health Care*. The tips rated most highly by beneficiaries, for example, became opening sentences for each of the five steps. The partnership removed many tips, such as a suggestion to ask providers about their hand-washing habits, not only in response to testing results, but also to create a more succinct, widely serviceable document.

After the original *Five Steps to Safer Health Care* patient fact sheet had been developed, representatives from CMS and other Federal agencies asked a number of additional questions: Would physicians welcome and distribute this patient fact sheet? Would a Spanish-language version of the fact sheet resonate as well as the English-language version? How and where should the patient fact sheet be disseminated and promoted? The following sections describe studies intended to address these concerns.

Physician testing

In July 2001, CMS retained a contractor to conduct four focus groups with 34 physicians in Baltimore and Philadelphia for the following purposes: to better understand their perceptions and beliefs regarding medical errors and patient safety, to obtain feedback on the content of the *Five Steps to Safer Health Care*, and to identify barriers to their use. The focus groups included both geriatricians (15 physicians with geriatrics specialization) and primary care physicians (19 internists, family and general practitioners) who work at least half their time with patients aged 65 and older.

While the physician respondents regarded the current media coverage of the “medical errors” topic as an attack on their practice, they generally considered the *Five Steps to Safer Health Care* to be “good medicine.” Indeed, the physicians thought the patient fact sheet could be a useful tool for emphasizing the patient’s responsibility for compliance and their role in health care safety.

Physicians also expressed some reservations for the patient fact sheet. Among the language changes suggested by physicians were a clearer differentiation of the surgeon, physician, and pharmacist roles, and a greater emphasis on the practice

of bringing a family member or friend to the physician's office. In addition, physicians expressed a reluctance to introduce and actively explore *Five Steps to Safer Health Care* and its various topics in patient encounters, due to professional time constraints and the absence of financial remuneration. They expressed a greater willingness to make the material available in their waiting area and to respond (or have their staff respond) to patient questions. These reactions suggested that developing ambulatory care materials that did not require active physician promotion might be a more effective strategy than developing materials that relied on a larger physician role.

Testing with consumers whose dominant language is Spanish

The Department of Health and Human Services translated the *Five Steps to Safer Health Care* into Spanish. A CMS contractor then back-translated the text, revised the document, and tested it in 26 one-on-one cognitive interviews during the spring of 2001. The interviews involved a wide range of Spanish-dominant (i.e., persons who prefer speaking in Spanish, regardless of their ability to speak English¹⁰) consumers in Washington, DC, and Miami, FL. Recruitment was designed to ensure variations across gender, ethnicity, age (32 to 75 years), educational attainment (8 with high school education or less, 18 with more), and country of origin (Puerto Rico, Colombia, El Salvador, Bolivia, Nicaragua, Ecuador, Panama, Cuba, Mexico, and Peru). The majority of interviewees were not Medicare beneficiaries, a recruitment decision made because the Spanish-speaking population in the nation is younger than the English-speaking population. In addition to testing how well consumers understood the text, researchers also asked respondents to describe their willingness to implement each described step.

Translation itself was not easy. The term "steps" could not be translated readily because the metaphor of climbing stairs as a forward-moving process was unfamiliar to the respondents. English-dominant beneficiaries were familiar with the terms "Ibuprofen" and "heart bypass surgery," but Spanish-dominant consumers were not familiar with them, regardless of whether they were presented in English or Spanish. Additionally, many of the respondents were unaware that their surgeon and primary care physician were not necessarily the same person.

Spanish-dominant consumers shared many of the attitudes revealed in consumer testing by the general Medicare population. These respondents wanted to work with, rather than confront, their health care providers. This testing also uncovered valuable information regarding cultural differences. For example, whereas the general population of Medicare beneficiaries indicated that they were reluctant to confront or contradict their physician, many Spanish-dominant consumers were uncomfortable even asking questions of their physician. Many did not know they could ask for their test results, and others indicated they would not follow up with the test results if they felt fine. Most also did not consider the

potentially harmful effects of combining prescription medications, over-the-counter medicines, or natural products. In Miami, respondents equated medical errors with fraud and abuse, perhaps reflecting the Spanish-language media attention given to such problems in that region of the country.

Spanish-dominant consumers recommended a number of changes to the text, reflecting their attitudes toward patient-physician interactions. In particular, respondents recommended the use of a writing voice that would reassure the reader of the importance of taking certain assertive steps. Phrases such as “It’s important that” (“Es importante que”), “You have the right to” (“Usted tiene el derecho de”), and “Make sure that” (“Asegúrese que”) were added to the Spanish version, but do not appear in the English version. “Heart operation” (“una operación de corazón”) was substituted for “heart bypass operation.” Additionally, readers were reminded that the surgeon and physician may be different people, and they were made aware of the importance of asking for test results, even if they feel fine.

Development and testing of promotional materials

As mentioned previously, physician testing of the *Five Steps to Safer Health Care* suggested that one approach to dissemination might be a “passive” distribution in the ambulatory care setting. Beginning in March 2003, CMS and its contractors, working with representatives of the Department of Defense, the Department of Veterans Affairs, and AHRQ, developed and tested promotional materials based on the *Five Steps to Safer Health Care*. Tested materials included a poster-sized version of the patient fact sheet, a series of “mini-posters” on each of the five steps, a tri-fold brochure, a medications reminder card (or “med card”), and a screensaver for medical office computers. Nine one-on-one interviews were conducted with physicians of various specialties, each receiving at least 10 Medicare patients per week. In addition, a focus group session was conducted with the following populations: Medicare beneficiaries aged 65 and older (12 subjects), informal caregivers of Medicare beneficiaries (i.e., caregivers with a family member dependent upon them for personal and supportive care) (11 subjects), registered nurses (9 subjects), and a nurse practitioner serving Medicare patients.

While some of the product prototypes (e.g., the screensaver) were discarded eventually, most were improved and developed. The research findings helped to clarify the language contained in them as well as in the original patient fact sheet. Step 4 in the fact sheet, for example, was modified to clarify a reference to a choice of hospitals, rather than a choice of treatments. The research also served to confirm earlier dissemination decisions. The potential for involving nurses in the patient education process and their willingness to respond to patient questions was explored with the use of the promotional materials. Nurses in the focus groups not only indicated their support for the *Five Steps to Safer Health Care*, saying it represented good medicine and promoted appropriate patient responsibility, but

they also actively and creatively sought out additional ways to empower consumers. In one particular promotional photograph, for example, male doctors were shown literally talking down to female patients, who were positioned at a lower height in the image. The nurses recommended replacing the image with one that showed female providers at the same level as the patients they were addressing. The recommended changes were intended to encourage patient comfort with the assertive behavior suggested in the fact sheet and promotional materials.

Annotated content from the five steps

To illustrate the aforementioned research strategy and the decisions that contributed to the current *Five Steps to Safer Health Care*, an annotated version of this patient fact sheet is provided below. Please note that the tool has been revised several times; the annotated text below reflects the most recent version, published in July 2004.

Title: *Five Steps to Safer Health Care*

The *20 Tips to Help Prevent Medical Errors* patient fact sheet refers to “medical errors.” However, the partner organizations that collaborated with Federal agencies on the Five Steps were concerned that the term “medical errors” would signify liability and negligence. These concerns were echoed by physicians who participated in subsequent research interviews.

Medicare beneficiaries, however, did not immediately comprehend the term “patient safety.” They thought it referenced falls and accidents of the sort that occurred in medical settings, rather than errors in care. Yet, after relatively little discussion, beneficiaries in focus groups generally believed the phrase “patient safety” could be used to signify medical error prevention in the general population. In the end, the English-language fact sheet title referred to “safer health care” because the phrase encouraged collaboration among providers, government agencies, and patients. The Spanish title refers to “getting better medical care,” due to the difficulties involved with translating “safer health care” into Spanish.

Step one: ask questions if you have doubts or concerns

- **Ask questions and make sure you understand the answers.**
- **Choose a doctor with whom you feel comfortable talking.**
- **Take a relative or friend with you to help you ask questions and understand the answers.**

The first step advises patients to ask questions. Beneficiaries strongly preferred tips that related to sharing information and collaborating with health care professionals. Spanish-dominant consumers, however, wanted more emphasis placed on the importance of patient questions and the need to ask them.

So, the Spanish version of the fact sheet adds the words, “It is important that you...” Despite physicians’ concerns for privacy, they endorsed the suggestion that patients bring someone along on office visits to help ask questions and understand the answers.

Step two: keep and bring a list of ALL the medicines you take

- **Give your doctor and pharmacist a list of all the medications that you take, including non-prescription medicines.**
- **Tell them about any drug allergies you have.**
- **Ask about side effects and what to avoid while taking the medicine.**
- **Read the label when you get your medicine, including all the warnings.**
- **Make sure your medicine is what the doctor ordered and know how to use it.**
- **Ask the pharmacist about your medicine if it looks different than you expected.**

Medications and adverse drug events are a key and often-cited patient safety topic that patient behavior can affect.^{11, 12} The second step highlights behaviors patients can use to decrease medication errors and improve patient-provider communication regarding, for example, nonprescription drugs and allergies. The second step also includes messages on medications that were reworded because beneficiaries perceived the originals as potentially confrontational (e.g., asking the pharmacist if the medication dispensed was what the physician ordered).¹⁰

Step three: get the results of any test or procedure

- **Ask when and how you will get the results of tests or procedures.**
- **Don’t assume the results are fine if you do not get them when expected, be it in person, by phone, or by mail.**
- **Call your doctor and ask for your results.**
- **Ask what the results mean for your care.**

The third step encourages patient activism to prevent potential communication gaps involving test results from compromising patient care. Research determined that many beneficiaries and other consumers whose predominant language is Spanish are reluctant to ask for test results and that they fail to follow up, especially if they feel well. The step also encourages patients to take responsibility for learning the implications of test results related to their care.

Step four: talk to your doctor about which hospital is best for your health needs

- **Ask your doctor about which hospital has the best care and results for your condition, if you have more than one hospital to choose from to get the health care you need.**
- **Be sure you understand the instructions you get about follow-up care when you leave the hospital.**

The fourth step addresses general hospital care, including hospital selection and discharge instructions.¹³ The text originally directed patients to choose a hospital with more experience in a procedure or surgery (i.e., “If you have more than one hospital to choose from, ask your doctor which one has the best care and results for your condition... [F]or some procedures [such as heart bypass surgery], research shows that results often are better at hospitals doing a lot of these procedures”). However, not every patient has the ability to use data to choose a high-volume hospital, and some might value hospital proximity or other characteristics more than experience. These considerations and the evolving literature regarding hospital and surgical volumes¹⁴ led to a less-specific suggestion: Patients should speak to their physicians about how to obtain the best results for their specific condition. Part of that discussion should address the topic of choosing the best hospital for the particular patient, if there is a choice of hospitals available. Beneficiaries participating in CMS-sponsored focus groups and interviews repeatedly suggested that the only choices they were aware of concerned treatment modalities, and not treatment settings. For this reason, they misinterpreted the original phrasing used in Step Four (“Talk... about your options if you need hospital care.”). Language in this step was changed to more clearly articulate the intended focus—hospital choice.

Step five: make sure you understand what will happen if you need surgery

- **Make sure you, your doctor, and your surgeon all agree on exactly what will be done during the operation.**
- **Ask your doctor, “Who will manage my care when I am in the hospital?”**
- **Ask your surgeon:**
 - **Exactly what will you be doing?**
 - **About how long will it take?**
 - **What will happen after the surgery?**
 - **How can I expect to feel during recovery?**
- **Tell the surgeon, anesthesiologist, and nurses about any allergies, bad reactions to anesthesia, and any medications you are taking.**

The fifth step offers questions that the patient can ask the physician and surgeon. The step encourages patients to work actively to understand the surgery, recovery, and coordination of care processes.¹³ It also encourages patients to ascertain that the multiple providers have communicated and are in agreement before surgery occurs. Physicians involved with the CMS study believed strongly that this step was needed to help patients better understand the different roles of pharmacists, physicians, and surgeons. Interviews with Spanish-dominant consumers further emphasized the need to clarify these roles. Additionally, the *20 Tips to Help Prevent Medical Errors* tells readers to “make sure” someone is in charge of their care. Testing feedback led to the transformation of this tip into a clearer action step, encouraging patients to ask for the name of the person who will manage their care while in the hospital.

Conclusion

The development of the *Five Steps to Safer Health Care* patient fact sheet and its associated promotional strategy and materials emerged from a successful collaboration between Federal agencies and private partners. The development and testing of the fact sheet illustrate research considerations worthy of other projects that aim to involve patients and other consumers in patient safety initiatives. Project directors may wish to ask themselves the following questions:

- What specific behaviors are we attempting to change?
- Who is the target audience, and what secondary audiences do we need to consider?
- If one is attempting to reach out to multiple cultures or persons whose primary language is not English, what differences between the populations need to be explored?
- What are the audiences’ beliefs and attitudes concerning patient safety, as well as those concerning health care providers, settings, and interactions between providers and patients?
- What barriers impede audience implementation of the behaviors we are attempting to change?
- What opportunities exist for communicating our key messages?

Finally, those who promote and disseminate the *Five Steps to Safer Health Care* and other consumer-oriented materials would benefit from evaluation research to address questions such as the following: What impact has the dissemination of documents such as the *Five Steps to Safer Health Care* had on patients and patients, physicians and nurses, in ambulatory and inpatient settings? What impact have similar documents authored by other organizations had, for example, on pharmacies and prescription practices? Research on these and related research questions could better enable the field to determine how to best integrate patient, health care provider, administrator, system, and payer interventions to improve the quality and safety of health care.

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